

# In the United States Court of Federal Claims

## OFFICE OF SPECIAL MASTERS

No. 20-0151V

UNPUBLISHED

N.B.,

Petitioner,

v.

SECRETARY OF HEALTH AND  
HUMAN SERVICES,

Respondent.

Chief Special Master Corcoran

Filed: June 13, 2023

Special Processing Unit (SPU);  
Dismissal; Insufficient Evidence;  
Tetanus, Diphtheria, acellular  
Pertussis (Tdap) Vaccine; Shoulder  
Injury Related to Vaccine  
Administration (SIRVA)

*Kathleen Margaret Loucks, Lommen Abdo Law Firm, Minneapolis, MN, for Petitioner.*

*Mark Kim Hellie, U.S. Department of Justice, Washington, DC, for Respondent.*

### **DECISION DISMISSING CASE**<sup>1</sup>

On February 13, 2020, N.B. filed a petition for compensation under the National Vaccine Injury Compensation Program, 42 U.S.C. §300aa-10, *et seq.*<sup>2</sup> (the “Vaccine Act”). Petitioner alleges that she suffered a left shoulder injury related to vaccine administration (“SIRVA”), a defined Table Injury, after receiving a tetanus-diphtheria-acellular pertussis (“Tdap”) vaccine on August 9, 2018. Petition at ¶¶ 1-3.

The record as it currently stands does not support Petitioner’s claim. Specifically, there is not only insufficient proof of a timely onset of Petitioner’s pain to establish a Table SIRVA (as I previously held), but also a lack of evidence of causation. Thus, because

<sup>1</sup> Because this Decision contains a reasoned explanation for the action taken in this case, it must be made publicly accessible and will be posted on the United States Court of Federal Claims’ website, and/or at <https://www.govinfo.gov/app/collection/uscourts/national/cofc>, in accordance with the E-Government Act of 2002. 44 U.S.C. § 3501 note (2018) (Federal Management and Promotion of Electronic Government Services). **This means the Decision will be available to anyone with access to the internet.** In accordance with Vaccine Rule 18(b), Petitioner has 14 days to identify and move to redact medical or other information, the disclosure of which would constitute an unwarranted invasion of privacy. If, upon review, I agree that the identified material fits within this definition, I will redact such material from public access.

<sup>2</sup> National Childhood Vaccine Injury Act of 1986, Pub. L. No. 99-660, 100 Stat. 3755. Hereinafter, for ease of citation, all section references to the Vaccine Act will be to the pertinent subparagraph of 42 U.S.C. § 300aa (2018).

Petitioner has failed to provide preponderant evidence to support a causation-in-fact version of the claim, the Petition is appropriately dismissed.

## I. Relevant Procedural History

The day after filing the Petition, N.B. filed an affidavit and the medical records required by the Vaccine Act. Exhibits 1-12, ECF No. 7; see Section 11(c). The case was subsequently activated and assigned to SPU. ECF No. 10.

During the initial status conference, held on April 16, 2020, the parties discussed evidence which appeared contrary to Petitioner's claim of pain onset beginning within 48 hours of vaccination. Order, issued Apr. 17, 2020, at 1-2, ECF No. 14. Respondent also noted the fall Petitioner experienced in February 2018 – approximately six months prior to vaccination - as a further complicating factor. *Id.* at 2. On July 2, 2020, Petitioner filed additional evidence addressing these issues and the question of causation – a letter from the second orthopedist seen approximately one-year post-vaccination, corrections to medical records made approximately two years post-vaccination (with one such request having been denied), and signed declarations<sup>3</sup> from her husband, three of her children, a paralegal at her law firm,<sup>4</sup> and herself. Exhibits 13-22, ECF No. 15.

On June 29, 2021, Respondent filed his Rule 4(c) Report opposing compensation in this case. ECF No. 25. Specifically, Respondent argued that Petitioner “has not provided preponderant evidence that the onset of her symptoms occurred within 48 hours of vaccination.” *Id.* at 9; *accord.* at 9-12. He also stressed that the medical records show Petitioner did not attribute her left shoulder pain to the Tdap vaccine until July 2019 – eleven months post-vaccination (*id.* at 10-11) - and further that she did not relate her shoulder pain to this vaccination until she read an article on SIRVA that was provided by her attorney (*id.* at 11).

In reaction, Petitioner filed supplemental declarations<sup>5</sup> from her husband and herself alleging that she had experienced pain on the night of vaccination, a note from

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<sup>3</sup> These declarations are signed under penalty of perjury in accordance with 28 U.S.C.A. § 1746. Although Petitioner previously provided a notarized affidavit (Exhibit 4), this filing is her first signed declaration. Exhibit 17. Additionally, these statements are the first signed declarations for her husband, children, and co-worker. Exhibits 18-22. Petitioner's husband later provided a second signed declaration. See *infra* note 5.

<sup>4</sup> Petitioner is an attorney. See, e.g., Exhibit 17 at ¶ 1 (Petitioner's first signed declaration).

<sup>5</sup> Like those filed in July 2020 (see *supra* note 3), these declarations are signed under penalty of perjury in accordance with 28 U.S.C.A. § 1746. Exs. 25-26. They will be referred to herein as the second signed declarations of Petitioner and her husband.

her primary care provider clarifying the date of vaccination, and a motion for a ruling on the record as it currently stood. Exhibits 25-26, filed Aug. 26, 2021, ECF No. 27; Exhibit 27, filed Aug. 30, 2021, ECF No. 29; Motion Petitioner's Motion for a Ruling on the Record, filed Aug. 31, 2021, ECF No. 31. During September 2021, Respondent filed a response, and Petitioner filed medical literature and a reply. Response to Motion, filed Sept. 14, 2021, ECF No. 32; Exhibits 28-29, filed Sept. 21, 2021, ECF No. 33; Petitioner's Reply, filed Sept. 21, 2021, ECF No. 35.

After determining that Petitioner has failed to provide evidence to establish onset within 48 hours of vaccination, I dismissed her Table SIRVA claim. Findings of Fact and Conclusions of Law Dismissing Table Claim ("Table SIRVA Dismissal"), filed July 19, 2022, ECF No. 37. However, I allowed Petitioner the opportunity to provide additional evidence to support a causation-in-fact claim. *Id.* at 13.

In response, Petitioner filed a status report, indicating "that she has no further evidence to present for her off table claim and relies on the briefing and evidence filed to date." ECF No. 41. She also filed a motion seeking redaction of her name and other information (ECF No. 38), which I granted in part (ECF No. 40).

The matter is now ripe for adjudication.

## **II. Applicable Legal Standards**

Under Section 13(a)(1)(A) of the Act, a petitioner must demonstrate, by a preponderance of the evidence, that all requirements for a petition set forth in section 11(c)(1) have been satisfied. A petitioner may prevail on her claim if the vaccinee for whom she seeks compensation has "sustained, or endured the significant aggravation of any illness, disability, injury, or condition" set forth in the Vaccine Injury Table (the Table). Section 11(c)(1)(C)(i).

If, however, the vaccinee suffered an injury that either is not listed in the Table or did not occur within the prescribed time frame, petitioner must prove that the administered vaccine caused injury to receive Program compensation on behalf of the vaccinee. Section 11(c)(1)(C)(ii) and (iii). In such circumstances, petitioner asserts a "non-Table or [an] off-Table" claim and to prevail, petitioner must prove her claim by preponderant evidence. Section 13(a)(1)(A). This standard is "one of . . . simple preponderance, or 'more probable than not' causation." *Althen*, 418 F.3d at 1279-80 (referencing *Hellebrand v. Sec'y of Health & Hum. Servs.*, 999 F.2d 1565, 1572-73 (Fed. Cir. 1993). The Federal Circuit has held that to establish an off-Table injury, petitioners must "prove . . . that the vaccine was not only a but-for cause of the injury but also a substantial factor in bringing about the injury." *Shyface v. Sec'y of Health & Hum. Servs.*, 165 F.3d 1344, 1351 (Fed.

Cir 1999). *Id.* at 1352. The received vaccine, however, need not be the predominant cause of the injury. *Id.* at 1351.

The Circuit Court has indicated that petitioners “must show ‘a medical theory causally connecting the vaccination and the injury’” to establish that the vaccine was a substantial factor in bringing about the injury. *Shyface*, 165 F.3d at 1352-53 (quoting *Grant v. Sec’y of Health & Hum. Servs.*, 956 F.2d 1144, 1148 (Fed. Cir. 1992)). The Circuit Court added that “[t]here must be a ‘logical sequence of cause and effect showing that the vaccination was the reason for the injury.’” *Id.* The Federal Circuit subsequently reiterated these requirements in its *Althen* decision. See 418 F.3d at 1278. *Althen* requires a petitioner

to show by preponderant evidence that the vaccination brought about her injury by providing: (1) a medical theory causally connecting the vaccination and the injury; (2) a logical sequence of cause and effect showing that the vaccination was the reason for the injury; and (3) a showing of a proximate temporal relationship between vaccination and injury.

*Id.* All three prongs of *Althen* must be satisfied. *Id.*

Finding a petitioner is entitled to compensation must not be “based on the claims of a petitioner alone, unsubstantiated by medical records or by medical opinion.” Section 13(a)(1). Further, contemporaneous medical records are presumed to be accurate and complete in their recording of all relevant information as to petitioner’s medical issues. *Cucuras v. Sec’y of Health & Hum. Servs.*, 993, F.2d 1525, 1528 (Fed. Cir. 1993). Testimony offered after the events in questions is considered less reliable than contemporaneous reports because the need for accurate explanation of symptoms is more immediate. *Reusser v. Sec’y of Health & Hum. Servs.*, 28 Fed. Cl. 516, 523 (1993).

### **III. Record As It Currently Stands Regarding Causation<sup>6</sup>**

I previously determined the record in this case supports a finding that Petitioner began experiencing intermittent left shoulder pain in late November or early December 2018, several months post-vaccination. Table SIRVA Dismissal at 11. As I cautioned Petitioner at that time, to succeed under a causation-in-fact claim, she needed to offer some evidence of causation consistent with my finding regarding onset.

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<sup>6</sup> I hereby incorporate the factual history and discussion set forth in my earlier ruling. See Table SIRVA Dismissal, ECF No. 37.

By Petitioner's own admission, she did not attribute her left shoulder pain to the Tdap vaccine she received in August 2018 until provided medical literature regarding SIRVA injuries by her attorney. Exhibit 17 at ¶ 5. And the contemporaneously-created medical records show Petitioner did not mention the Tdap vaccine as a potential cause for her left shoulder pain until an appointment with her primary care provider on July 10, 2019, almost a year post-vaccination. Exhibit 6 at 35-36. At multiple earlier appointments from late December 2018 through April 2019, Petitioner reported no known cause for her left shoulder pain. See, e.g., Exhibit 8 at 81 (reporting intermittent left shoulder pain which "[l]asts only minutes," intermittent "charlie horses" in her feet, and a failure to "drink much water" at an annual physical on December 21, 2018); Exhibit 11 at 5 (denying "any direct injury of previous surgery or radiculopathy" at February 20, 2019 orthopedic visit); Exhibit 11 at 13 (reporting general left shoulder pain "with no known MOI<sup>7</sup>" at first physical therapy session on March 4, 2019).

Similarly, none of the physicians who treated Petitioner before August 2019 mentioned this earlier Tdap vaccination as a potential cause for her left shoulder pain. Instead, they diagnosed Petitioner as suffering from bursitis, osteoporosis, and left shoulder impingement with underlying adhesive capsulitis; provided a handout on bursitis; and ordered osteoporosis therapy, magnesium oxide or tonic water, and an MRI. Exhibit 8 at 84-85; Exhibit 11 at 8.

The only evidence which supports a causation-in-fact claim is the opinion of the second orthopedist Petitioner first saw in August 2019 (a year after vaccination). Exhibit 13. Although he did opine that Petitioner's pain was due to the vaccine she received, the orthopedist clearly relied upon Petitioner's assertion that she had suffered left shoulder pain since the time of vaccination, rather than later. See Exhibit 13 (letter from this second orthopedist); Exhibit 7 at 1-11 (first visit to this second orthopedist). It has not been established that he was ever provided with or reviewed any *other* evidence relevant to this opinion – such as Petitioner's medical records and earlier-provided medical histories. And it is facially contrary to my onset fact determination.

Treater opinions do not receive evidentiary weight in the Program when they are based on incorrect facts. *Snyder v. Sec'y of Health & Hum. Servs.*, No. 01–0162V, 2009 WL 332044, at \*187 n.523 (Fed. Cl. Spec. Mstr. Feb. 12, 2009), *mot. for review den'd*, 88 Fed. Cl. 706 (2009) (discussing the importance of an accurate factual basis for any treating physician or expert opinion). A special master may thus reject expert opinion if based "on facts not substantiated by the record." *Burns v. Sec'y of Health & Hum. Servs.*, 3 F.3d 415, 417 (Fed. Cir. 1993). Accordingly, for any treating physician opinion to be credible, it must be shown to have been based upon all relevant evidence in this case,

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<sup>7</sup> MOI stands for mechanism of injury. MEDICAL ABBREVIATIONS at 384 (16<sup>th</sup> ed. 2020).

including Petitioner's complete medical records - unrevised and revised versions.<sup>8</sup> Due to its faulty foundation and reliance on an assumption I have previously rejected, the orthopedist's opinion lacks probative value.

As shown by the handout and medical literature Petitioner supplied, an onset of pain very close in time to vaccination is key to a SIRVA diagnosis. Exhibit 17 at 7 (handout citing the Atanasoff article); Exhibit 28 at 2 (Atanasoff article). Almost all individuals suffering a SIRVA injury experienced pain within 24 hours of vaccination, with approximately 50 percent experiencing *more* immediate pain. *Id.* Because this case does not involve such an immediate onset, Petitioner was required to provide preponderant evidence establishing that pain manifesting three months after vaccine administration was reflective of a SIRVA injury. But Petitioner has failed to provide even a minimal amount of evidence showing that the left shoulder pain she experienced in the fall of 2018 and later was caused by the Tdap vaccine she received in August 2018 – and that a SIRVA-like injury could so arise even if several months after vaccination. Therefore, the entire petition will be dismissed.

### **Conclusion**

To date, and despite ample opportunity, Petitioner has failed to provide preponderant evidence to support her allegation of a left shoulder injury which meets the Table SIRVA definition. Nor can she preponderantly establish that her injury was more likely than not caused by the Tdap vaccine she received on August 9, 2018. Petitioner was informed that failure to provide preponderant to support her claim would be treated as either a failure to prosecute this claim or as an inability to provide supporting documentation for the claim.

Accordingly, this case is DISMISSED for failure to prosecute and insufficient evidence. The Clerk of Court shall enter judgment accordingly.<sup>9</sup>

**IT IS SO ORDERED.**

**s/Brian H. Corcoran**

Brian H. Corcoran  
Chief Special Master

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<sup>8</sup> See *Isaac v. Sec'y of Health & Hum. Servs.*, No. 08-601V, 2012 WL 3609993, at \*17 (Fed. Cl. Spec. Mstr. July 30, 2012), *mot. for rev. denied*, 108 Fed. Cl. 743 (2013), *aff'd*, 540 F. Appx. 999 (Fed. Cir. 2013) (discussing the factors to be considered when weighing the value of a treating physician's opinion).

<sup>9</sup> Pursuant to Vaccine Rule 11(a), entry of judgment can be expedited by the parties' joint filing of notice renouncing the right to seek review.